

REMARKS

I. Responses to Examiner's Remarks

Applicants appreciate the Examiner's careful attention to this application. Reconsideration of the application is respectfully requested.

Claims 1-12, 14, 16, 19-29 and 31-35 are pending. Claims 1, 2, 6-12, 14, 21-29 and 31-35 are withdrawn from consideration. Claims were rejected in the Office Action as failing to meet one or more of the requirements of 35 U.S.C. § 112. Applicants are pleased to note that the references identified in the search are considered by the Office to neither anticipate nor render obvious any claim currently under consideration.

II. Discussion of Amendments (Support Identified)

Applicants have made amendments to the claims. Applicants submit that no new matter has been added to the claims. Applicants have made these amendments for the sole purpose of facilitating the expeditious allowance of any subject matter identified as allowable by the Examiner. Applicants make no admission herein that any cancelled or amended claims in their original form is non-patentable, nor do Applicants disclaim the subject matter of any cancelled or amended claims or dedicate them to the public. If any such disclaimers are believed to have been made, Applicants explicitly rescind them for the purpose of future applications to permit recapture of the original subject matter of any cancelled or amended claims. Applicants reserve the right to file future applications for letters patent directed to the original subject matter of any cancelled or amended claims. Support for the amendments may be found in the specification as originally filed as discussed below. Paragraph numbers refer to the published version of the Application,

unless stated otherwise.

Claim 1 has been amended. Claim 1 now recites “a preparation comprising at least 30% by weight” of the listed polypeptides. This element is found in the specification at least in paragraph [0061] of the published application.

Claim 1 now recites an LKB1 polypeptide that phosphorylates or activates AMPK. The specification teaches that LKB1 activates and phosphorylates AMPK at least in paragraphs [0333]-[0337] of the published application.

Claim 1 now recites an LKB1 polypeptide comprising a catalytically active domain comprising a sequence selected from the group consisting of: residues 44-343 of SEQ ID NO: 6, a variant thereof having a conservative substitution, and a variant thereof having at least 65% sequence homology. The specification teaches an LKB1 polypeptide with a catalytically active domain at least in paragraph [0023] of the published application. The specification teaches that the catalytic domain of LKB1 is found from about residue 44 to about residue 343 at least in paragraphs [0137], [0142], [0169], and [0186]. The specification teaches variants having conservative substitutions at least in paragraphs [0029] and [0030]. The specification teaches variants having at least 65% sequence homology at least in paragraph [0032].

Claim 1 now recites a STRAD polypeptide that binds to LKB1 and MO25, and comprises a C-terminal pseudokinase domain comprising the C-terminal sequence Trp-Glu-Phe. The element of a C-terminal sequence Trp-Glu-Phe is taught by the specification at least in paragraphs [0140], [0161], [0168], [0173], and [0174]. The element of STRAD binding LKB1 and MO25 is taught by the specification at least in paragraph [0026].

Claim 1 now recites an MO25 polypeptide that binds STRAD and comprises a sequence selected from the group consisting of: SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, a variant of any of the foregoing having a conservative substitution, and a variant of any of the foregoing having at least 65% sequence homology. The specification teaches the element of MO25 binding STRAD at least in paragraph [0026]. The specification teaches the element of the listed sequences at least in Figure 2. The specification teaches variants having conservative substitutions at least in paragraphs [0029] and [0030]. The specification teaches variants having at least 65% sequence homology at least in paragraph [0032].

Claim 19 has been amended. Claim 19 now recites the steps of contacting a substrate polypeptide with a LKB1-STRAD-MO25 complex and measuring the phosphorylation of the substrate polypeptide. The interaction between LKB1 and substrates is taught in the specification at least in original Claim 20, paragraphs [0004], [0011], and the Examples. The specification teaches the element of measuring the phosphorylation of the substrate at least in paragraph [0011], [0013], [0044], [0139], [0147], [0153], and [0155].

Claim 19 now recites substrate that is myelin basic protein or a polypeptide comprising one of the following sequences: SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 33, SEQ ID NO: 35, SEQ ID NO: 110, a variant thereof having a conservative substitution, and a variant thereof having at least 65% sequence homology. The specification teaches the element of a substrate for LKB1 that is SEQ ID NO: 17-21 at least on page 30, lines 14-

26 of the specification, as amended on 28 November 2008 (see page 3 of the amendment). The specification teaches the element of a substrate for LKB1 that is SEQ ID NO : 16, 17, 18, 19, 20, 21, 23, 24, 25, 23, 29, 31, 33, 35 or 37 at least in the paragraph bridging pages 40 and 41 as amended on 28 November 2008 (see page 4 of the amendment). The specification teaches the element of a substrate for LKB1 that is SEQ ID NO: 110 at least on page 121 lines 19-21 of the specification as amended on 28 November 2008 (see page 16 of the amendment). The specification teaches the element of a substrate for LKB1 that is myelin basic protein at least in paragraphs [0007], [0020], [0025], [0046], [0099], [0172], and [0163].

Claim 19 now recites that the LKB1-STRAD-MO25 complex comprises a LKB1 polypeptide that phosphorylates or activates AMPK, and comprises a catalytically active domain comprising at least one of: residues 44-343 of SEQ ID NO: 6, a variant thereof having a conservative substitution, and a variant thereof having at least 65% sequence homology. The specification teaches an LKB1 polypeptide with a catalytically active domain at least in paragraph [0023] of the published application. The specification teaches that the catalytic domain of LKB1 is found from about residue 44 to about residue 343 at least in paragraphs [0137], [0142], [0169], and [0186]. The specification teaches variants having conservative substitutions at least in paragraphs [0029] and [0030]. The specification teaches variants having at least 65% sequence homology at least in paragraph [0032].

Claim 19 now recites that the LKB1-STRAD-MO25 complex comprises a STRAD polypeptide that binds to LKB1 and MO25, and comprises a C-terminal pseudokinase domain comprising the C-terminal sequence Trp-Glu-Phe. The element of

a C-terminal sequence Trp-Glu-Phe is taught by the specification at least in paragraphs [0140], [0161], [0168], [0173], and [0174]. The element of STRAD binding LKB1 and MO25 is taught by the specification at least in paragraph [0026].

Claim 19 now recites that the LKB1-STRAD-MO25 complex comprises an MO25 polypeptide that binds STRAD and comprises a sequence selected from the group consisting of: SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, a variant of any of the foregoing having a conservative substitution, and a variant of any of the foregoing having at least 65% sequence homology. The specification teaches the element of MO25 binding STRAD at least in paragraph [0026]. The specification teaches the element of the listed sequences at least in Figure 2. The specification teaches variants having conservative substitutions at least in paragraphs [0029] and [0030]. The specification teaches variants having at least 65% sequence homology at least in paragraph [0032].

As it is believed that the amendments introduce no new matter to the claims and as the amendment is made timely prior to the issuance of a final office action on the merits after a request for continued examination, it is respectfully requested that the amendment be entered.

III. CLAIM REJECTIONS

A. Indefiniteness Rejections Under 35 U.S.C. § 112, Paragraph 2

On pages 2-4 of the Office Action, Claims 3-5, 16, 19 and 20 were rejected as indefinite on three distinct grounds. Applicants respectfully traverse.

The Office Action states on page 2 that Claims 3-5, 16, 19 and 20 are indefinite because the phrase “A purified preparation, comprising LKB1, STRAD, and recombinant

MO25” is not adequately defined. Applicants respectfully submit that the claims are not indefinite.

Claim 3 recites “an LKB1 polypeptide” that phosphorylates or activates AMPK, and comprises a catalytically active domain comprising at least one of: residues 44-343 of SEQ ID NO: 6, a variant thereof having a conservative substitution, and a variant thereof having at least 65% sequence homology. One of ordinary skill in the art at the time of filing would have understood what is meant by an LKB1 polypeptide having these particular properties and structure; therefore the claim is not indefinite.

Claim 3 recites “a STRAD polypeptide” that binds to LKB1 and MO25, comprises a C-terminal pseudokinase domain, said C-terminal pseudokinase domain comprising the C-terminal sequence Trp-Glu-Phe. One of ordinary skill in the art at the time of filing would have understood what is meant by a STRAD polypeptide having these particular properties and structure; therefore the claim is not indefinite.

Claim 3 recites an MO25 polypeptide that binds to STRAD, and comprises a sequence selected from the group consisting of: SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, a variant of any of the foregoing having a conservative substitution, and a variant of any of the foregoing having at least 65% sequence homology. One of ordinary skill in the art at the time of filing would have understood what is meant by an MO25 polypeptide having these particular properties and structure; therefore the claim is not indefinite.

The Office has taken the position that the term “purified” is not sufficiently described in the specification. Applicants have amended Claim 3 to recite “A preparation comprising at least 30% by weight” of the proteins. Applicants submit that a person of

ordinary skill in the art would have understood what is meant by “at least 30% by weight” at the time of filing; therefore the claim is not indefinite.

The Office Action states on page 3 that Claim 19 is indefinite because Claim 19 recites no steps to test whether or not a compound is effective at modulating LKB1 activity in a cellular context. Claim 19 as amended recites the steps of contacting a substrate polypeptide with a LKB1-STRAD-MO25 complex and measuring the phosphorylation of the substrate polypeptide. Applicants submit that a person of ordinary skill in the art would have understood what is meant by the listed steps at the time of filing; therefore the claim is not indefinite.

The Office Action states on page 4 that Claims 19 and 20 are indefinite for recitation of the phrase “a preparation according to claim 3” instead of “the preparation according to claim 3.” Applicants corrected this error in the response of 25 August 2009.

The Office Action states on page 4 that Claim 20 is indefinite for recitation of the term “the substrate” without antecedent basis. Applicants have amended Claim 20 to correct the rejected language. Applicants corrected this error in the response of 25 August 2009.

Applicants respectfully request reconsideration of the rejections. As explained above, the claims were not indefinite to one of ordinary skill in the art at the time of filing. Accordingly, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

B. Enablement Rejections Under 35 U.S.C. § 112 Paragraph 1

On pages 4-5 of the Office Action, Claims 3-5, 16, 19 and 20 were rejected as non-enabled by the specification. Applicants respectfully traverse.

The Office has taken the position that a person of ordinary skill in the art at the time of filing would be unable to practice the claimed compositions, kits, and methods without undue experimentation because of the broad interpretation given to the terms LKB1, STRAD, and MO25. Applicants respectfully submit that the claims as amended now recite structures and functions of these polypeptides, and one of ordinary skill in the art at the time of filing could have made or used the claimed compositions, kits, and methods without undue experimentation.

Applicants respectfully request reconsideration of the rejections. As explained above, the claims could have been practiced without undue experimentation by one of ordinary skill in the art at the time of filing. Accordingly, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

C. Written Description Rejections Under 35 U.S.C. § 112 Paragraph 1

On page 6 of the Office Action, Claims 3-6, 16, 19 and 20 were rejected under the written description requirement. Applicants respectfully note that the Office has previously taken the position that Claim 6 is withdrawn; Applicants therefore do not address the rejection of Claim 6 on this basis in this response.

The claims are rejected for the stated reason that “the specification fails to disclose the genus of any ‘purified preparation’ comprising any LKB1, STRAD, and MO25 proteins, having any structure, as encompassed by the instant claims, such that the skilled artisan would recognize that Applicants were in possession of the invention at the time of filing.”

Applicants respectfully point out that the term “purified preparation” has been deleted from the claims. As the rejected term has been deleted, this aspect of the

rejection is moot. Likewise the rejected claims now recite particular structures and functions of LKB1, STRAD, and MO25, so that they no longer encompass “any structure.” As the claims have been amended to comply with the rejection, Applicants respectfully submit that this aspect of the rejection is now moot as well.

Applicants respectfully request reconsideration of the claims. The claimed embodiments are described sufficiently that one of ordinary skill in the art at the time of filing would have understood that Applicants were in possession of the claimed embodiments. Accordingly, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

CONCLUSION

Applicants respectfully request the Commissioner of Patents consider the enclosed remarks and enter the following submission into the record, in response to the Office Action dated 2/25/2009. Reconsideration in light of this submission is respectfully requested. If the Examiner requires additional action that may benefit from a telephone call, Applicants invite a call to its attorney of record, Nicholas J. Landau (Reg. No. 57,120). E-mail correspondence and transactions to nlandau@babco.com are authorized and encouraged.

Applicants have diligently sought to comply with all requirements and to correct all informalities and rejections. The Application is believed to be in condition for allowance, and a timely Notice of Allowance is respectfully requested.

Respectfully submitted,
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23 Sep. 2009
Date

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